IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DONNA HORNBECK and JOHN HORNBECK,	)	
Plaintiffs,	)	13 C 7816
v.	)	
	)	Judge Virginia M. Kendall
MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK, USA, and TRAVIS RICHARDSON, M.D.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Defendants Medtronic, Inc. and Medtronic Sofamor Danek, USA, Inc. move to dismiss the claims asserted against them by the Plaintiffs. The Plaintiffs filed an eleven-count complaint against the Medtronic Defendants and a third defendant, Dr. Travis Richardson. The Plaintiffs' claims stem from Plaintiff Donna Hornbeck's August 8, 2011, spinal surgery during which Dr. Richardson implanted a product designed and manufactured by the Medtronic Defendants. The product is a Class III medical device regulated by the Food and Drug Administration. The Medtronic Defendants claim that federal law expressly and impliedly preempts the Plaintiffs' claims. The Medtronic Defendants further claim that the medical community's knowledge of the risks associated with the Medtronic Defendants' product preclude the Plaintiffs' failure-to-warn claims, the Medtronic Defendants' warranty disclaimers preclude the Plaintiffs' warranty claims, and that the Plaintiffs have not pled fraud with particularity. For the reasons stated herein, this Court denies the Medtronic Defendants' motion.

FACTS

This Court takes the following well-pleaded allegations from the Complaint and treats them as true for purposes of this motion.

The FDA approved the Medtronic Defendants' premarket approval application for the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device on July 2, 2002. (Dkt. No. 1 at ¶ 27.) Together, these two components include a tapered metallic spinal fusion cage, a recombinant human bone morphogenetic protein, and a carrier/scaffold for the bone morphogenetic protein and resulting bone. (*Id.* at ¶ 28.) The use approved by the FDA requires these two components, the InFUSE® Bone Graft and the LT-CAGE™ Lumbar Tapered Fusion Device, to be used together. (*Id.* at ¶ 29.) The InFUSE® Bone Graft component helps form bone to stabilize the diseased region of the spine permanently and the LT-CAGE™ Lumbar Tapered Fusion Device spaces and stabilizes that region of the spine while the bone forms. (*Id.* at ¶ 30.)

The FDA approved the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device for an Anterior Lumbar Interbody Fusion procedure involving a single-level fusion in the L4-S1 region of the lumbar spine. (*Id.* at ¶ 35.) This procedure, which treats pain resulting from degenerative disc disease, requires an incision in the abdomen. (*Id.*) The FDA did not approve the InFUSE® Bone Graft component for use in spinal fusion surgeries without the LT-CAGE™ Lumbar Tapered Fusion Device or in posterior lumbar fusion procedures. (*Id.* at ¶ 36.)

Even though the use approved by the FDA requires specific components used together in a specific procedure, sales representatives for the Medtronic Defendants promoted the InFUSE® Bone Graft component for other uses. (*Id.* at ¶ 132.) In addition, the Medtronic Defendants used royalty and consulting agreements with opinion leaders in the field to influence other surgeons to use the InFUSE® Bone Graft component in a manner not approved by the FDA. (*Id.* at ¶ 133.) These efforts were part of the Medtronic Defendants' plan to expand the use of the InFUSE®

Bone Graft component beyond that approved by the FDA. (*Id.* at ¶ 136.) These efforts included misrepresentations and intentional omissions of risks involved when using the InFUSE® Bone Graft component in a manner not approved by the FDA. (*Id.* at ¶ 177.)

While promoting the InFUSE® Bone Graft component, the Medtronic Defendants did not report adverse events to the FDA. (*Id.* at ¶¶ 216-219.) And despite evidence of foreseeable risks such as bone overgrowth and radiculitis, the Medtronic Defendants downplayed or did not warn surgeons of those risks. (*See, e.g., id.* at ¶¶ 220-221.) Further, the Medtronic Defendants deceived the medical community by manipulating the medical literature regarding InFUSE® Bone Graft component to misrepresent the product's safety and efficacy. (*Id.* at ¶ 222.) The Plaintiffs claim that these acts violated federal statutes and regulations. (*Id.* at ¶ 129.)

On August 8, 2011, Dr. Richardson implanted the InFUSE® Bone Graft component in Donna Hornbeck using a Transforaminal Lumbar Interbody Fusion procedure. (*Id.* at ¶ 332.) This procedure involved a posterior approach, did not involve the LT-CAGE™ Lumbar Tapered Fusion Device, and affected more than one level in the lumbar spine. (*Id.*) Plaintiff Donna Hornbeck subsequently experienced pain in the left side of her back that radiated down her left leg as well as numbness and tingling in her left leg. (*Id.*) Subsequent surgical procedures were necessary to address these issues. (*Id.* at ¶ 336.)

The Plaintiffs filed their Complaint on October 31, 2013. Donna Hornbeck alleges the following against the Medtronic Defendants: (1) fraudulent misrepresentation and fraud in the inducement (Count I); (2) strict products liability – failure to warn (Count II); (3) strict products liability – design defect (Count III); (4) strict products liability – misrepresentation (Count IV); (5) product liability – negligence (Count V); (6) breach of express warranty (Count VI); and (7)

breach of implied warranties of merchantability and fitness (Count VII). Plaintiff John Hornbeck alleges loss of consortium against all of the Defendants.

LEGAL STANDARD

Federal law protects Class III medical device manufacturers who subject their devices to the premarket approval process from civil liability so long as the manufacturers comply with federal law. *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010). The Food, Drug, and Cosmetic Act ("FDCA") provides federal oversight of medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008) (discussing Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.*). Through the premarket approval process, the Food and Drug Administration evaluates the safety and effectiveness of a proposed medical device, determines whether a manufacturer may market that device, and decides whether to impose any restrictions on that device. *See id.* at 318 (discussing premarket approval process).

The FDCA expressly preempts any state or local requirement with respect to a medical device that is "different from, or in addition to" the requirements applicable under the FDCA and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA. 21 U.S.C. § 360k; *see also Riegel*, 552 U.S. at 516 (discussing 21 U.S.C. § 360k). This preemption provision, however, does not impliedly preempt all state-law claims based on the FDCA. *Bausch*, 630 F.3d at 557. Rather, well-recognized state-law claims grounded in a state's historic police powers may proceed so long as a violation of the FDCA caused the harm to the plaintiff. *Id.* at 557-58 (reversing dismissal of state-law claims for negligence and strict liability based on manufacture of Class III medical device in violation of federal law).

There are no special pleading requirements for product liability claims involving Class III medical devices. *Bausch*, 630 F.3d at 558. Generally, a plaintiff need only allege sufficient facts

to state a claim for relief that is plausible on its face. *Id.* (citing *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)). A fraud claim, however, requires a plaintiff to state with particularity the circumstances constituting fraud. Fed. R. Civ. P. 9(b); *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 615 (7th Cir. 2011) ("This ordinarily requires describing the 'who, what, when, where, and how' of the fraud, although the exact level of particularity that is required will necessarily differ based on the facts of the case.").

DISCUSSION

I. Premption

The FDCA does not preempt the Plaintiffs' claims. Donna Hornbeck asserts seven claims against the Medtronic Defendants. All of her claims are state-law claims premised on alleged violations of the FDCA. John Hornbeck's state-law claim for loss of consortium derives from Donna Hornbeck's claims and, therefore, his claim rises or falls with her claims. None of the Plaintiffs' claims imposes requirements different from or in addition to those imposed by the FDCA. Therefore, the Plaintiffs' state-law claims premised on violations of the FDCA may proceed.

Because preemption is an affirmative defense properly raised under Fed. R. Civ. P. 12(c), *see Bausch*, 630 F.3d at 546, this Court will treat the Medtronic Defendants' preemption arguments as a motion for judgment on the pleadings. There is no question that the FDA has imposed regulations on the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. Consequently, the only question with respect to express preemption is whether the Plaintiffs' state law claims impose regulations that are different from or in addition to those imposed by the FDCA and the FDA.

According to the Medtronic Defendants, several of the Plaintiffs' claims would require warnings in addition to those specified by the FDA. But this argument misconstrues the

Plaintiffs' claims because it assumes that the Plaintiffs based their claims on the use of the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device approved by the FDA. It is true that if the Medtronic Defendants marketed and promoted the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device for the use approved by the FDA and in the manner required by the FDA, then the only warnings necessary would be those imposed by the FDA. The gravamen of the Plaintiffs' claims, however, is that the Medtronic Defendants marketed and promoted the InFUSE® Bone Graft component in contravention of the FDA's requirements. To the extent that the Medtronic Defendants failed to market and promote their device as required by the FDA, then they have also removed themselves from whatever protection federal oversight of medical devices would have provided. Logic dictates that if the use marketed and promoted by the Medtronic Defendants was different from or in addition to that approved by the FDA, then the warnings necessary may well be in addition to those required by the FDA. In short, the FDA considered a specific use and issued specific warnings for that use. It does not follow that the FDA's oversight with respect to that specific use protects all other uses. Accordingly, the FDCA does not preempt the Plaintiffs' claims premised on the duty to warn others about risks associated with unapproved uses of the InFUSE® Bone Graft component the Medtronic Defendants marketed and promoted.

The FDA's approved use requires one to use the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device together as a system. Implicit in this requirement is that the FDA reviewed and approved the InFUSE® Bone Graft component in conjunction with the LT-CAGE™ Lumbar Tapered Fusion Device. Although the FDA discusses the features of each component individually, this Court must take all inferences in the Plaintiffs favor. When doing so, the requirement that one use the two components together suggests that the FDA considered

the design of the two components together notwithstanding its decision to allow the Medtronic Defendants to sell the components separately. Therefore, the FDCA does not preempt the Plaintiffs' claims premised on any design defect associated with the use of the InFUSE® Bone Graft component alone.

Because the FDA's approved use requires one to use the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device together as a system, it follows that the FDA considers the two safe and effective when used together. In other words, there is no indication that the FDA considered either component as safe and effective when used independent of the other. If anything, the requirement that one use the two components together suggests that use of one without the other is not safe and effective. It is simply disingenuous for the Medtronic Defendants to argue that the Plaintiffs seek to enforce safety requirements different from or in addition to those imposed by the FDA when the FDA imposed those requirements on the two components used together. The Plaintiffs' claims allege that the Medtronic Defendants not only marketed and promoted the InFUSE® Bone Graft component alone, but also failed to report adverse events based on that use to the FDA as required.

It is also disingenuous for the Medtronic Defendants to suggest that preemption applies because physicians are free to use the device as they deem appropriate. It is true that the FDCA does not regulate the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001); *see also Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC*, 589 F.3d 881, 884 (7th Cir. 2009) (off-label use is a professional judgment for the healthcare provider to make). But that is not at issue with respect to the Medtronic Defendants. What is at issue is how the Medtronic Defendants' marketed and promoted the InFUSE® Bone Graft component. The FDA does regulate the Medtronic Defendants' marketing and promotion of the

InFUSE® Bone Graft component. *See, e.g., id.*at 884 (explaining that medical device manufacturer ran afoul of the FDA by promoting the device for unapproved use). To the extent that the Medtronic Defendants' failed to comply with federal requirements, the Plaintiffs may proceed with their claims.

Illinois law considers federal violations as evidence of violations of duties imposed by state law. *See Bausch*, 630 F.3d at 553 ("Illinois treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence, though the violation may not always be conclusive on the issue of negligence."); *Martin by Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 355 (Ill. 1996) ("This court has suggested that FDA regulations may be relevant in determining whether a manufacturer has complied with its existing common law duty to provide warnings to physicians pursuant to the learned intermediary doctrine.") (emphasis omitted). Contrary to the Medtronic Defendants' assertion, the Plaintiffs are not attempting to enforce the FDCA. Instead, the Plaintiffs' seek to vindicate rights protected by state law that the Medtronic Defendants' allegedly violated when they failed to comply with federal requirements. To the extent that the Plaintiffs' claims do not impose any requirements different from or in addition to federal requirements, and because the Plaintiffs' claims seek to vindicate rights protected by state law, neither express preemption nor implied preemption applies.

Although the Medtronic Defendants cite a number of cases that conclude otherwise, none of those cases is persuasive to or binding on this Court. More importantly, those cases contradict the guidance set forth in precedent that is binding on this Court. *Bausch* makes clear that the notion that medical device manufacturers can violate federal law in ways that result in harm to patients yet remain immune to suit does not make sense. *Bausch*, 630 F.3d at 549. A medical

device manufacturer receives no protection where a plaintiff can prove that the manufacturer's violation of federal law caused his or her injury compensable under state law. *Id.*at 550. Here, the Plaintiffs have alleged that the Medtronic Defendants' have violated several federal requirements and those violations serve as the bases of the Plaintiffs' state-law claims. Therefore, this Court denies the Medtronic Defendants' preemption motion.

II. Motion to Dismiss

The Medtronic Defendants also move to dismiss several of the Plaintiffs' claims for failure to state a claim. The Medtronic Defendants claim that the learned intermediary doctrine precludes any claim based on their alleged duty to warn physicians. "A medical device manufacturer has no duty to warn physicians of a device's dangers which the medical community generally appreciates." *Hansen v. Baxter Healthcare Corp.,* 723 N.E.2d 302, 312 (1999). But the Plaintiffs allege that the Medtronic Defendants engaged in a misinformation campaign that prevented the medical community from truly appreciating the risks associated with the InFUSE® Bone Graft component. Allegations such as this preclude dismissal based on the learned intermediary doctrine.

Further, uncertainty as to the scope of any disclaimer on the approved label precludes dismissal. At this stage, the Court must take all inferences in the Plaintiffs' favor. Here, the approved label requires one to use the InFUSE® Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device together as a system. Although the warranty disclaimer in that same label is silent as to combined use, one could infer that the disclaimer extends only to the use described in the label. One could also infer that the Medtronic Defendants, through their marketing and promotion of the InFUSE® Bone Graft component, to include their alleged sponsorship of favorable yet questionable research, created express warranties as to the quality of the InFUSE®

Bone Graft component under 810 ILCS 5/2-313. Therefore, this Court will not dismiss the Plaintiffs' warranty claims.

Nor will this Court dismiss the Plaintiffs' fraud claims. The Complaint details an elaborate campaign to manipulate the medical community as to the safety and efficacy of a use of the InFUSE® Bone Graft component that the FDA did not approve. Notwithstanding the Plaintiffs' unnecessary and extensive discussion of the relevant statutes and regulations, the Complaint addresses the who, what, when, where, why, and how of the Medtronic Defendants' alleged fraud. This Court finds that the Plaintiffs' have pleaded their fraud claims with sufficient particularity.

This Court also finds that the Plaintiffs' have pleaded the Medtronic Defendants' alleged failure to report adverse events. As *Bausch* explained, "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Bausch*, 630 F.3d at 558. This is particularly true where information is likely to be kept confidential. *Id.* As it stands, the Plaintiffs have allegations suffice to provide the Medtronic Defendants with fair notice of their claims. That is generally all that is required. *See id.* at 562.

CONCLUSION

For the reasons stated herein, this Court denies the Medtronic Defendants' motion to dismiss.

Virginia M. Kendall

Virginia M. Kendall
United States District Court Judge
Northern District of Illinois

Date: June 2, 2014